

12D



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,369	08/27/2003	Andrew A. Potter	9000-0057.01	7295
20855	7590	06/03/2004	EXAMINER	
ROBINS & PASTERNAK 1731 EMBARCADERO ROAD SUITE 230 PALO ALTO, CA 94303			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/650,369	Applicant(s) POTTER ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-45 and 60-62 is/are pending in the application.
- 4a) Of the above claim(s) 37-45 and 60-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-14, 19-23 and 28-32 is/are rejected.
- 7) ☒ Claim(s) 15-18, 24-27 and 33-36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8-27-2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, and the invention represented by SEQ ID NO: 21 in the paper filed on March 22, 2004 is acknowledged.
2. Currently, claims 10-45, and 60-62 are pending. In the Response to the restriction requirement, the Applicant cancelled claims 4-9, 46-59, and 63-75 from the application.
3. Claims 37-45, and 60-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed on March 22, 2004.
4. Currently, claims 10-36 are under consideration to the extent that they read on the elected invention.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on August 27, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Objections

6. Claim 10 is objected to because of the following informalities: it is suggested that the term "epitope" in line 3 of the claim be replaced with the term - - epitopes- - to reflect that multiple epitopes are required by the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 10, 13, 14, 19, 22, 23, 28, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 6,063,386, issued to Dale et al. (Dale), in view of WO document 93/14198, naming Fischetti et al. as inventors (Fischetti), in light of Hafid et al., Comparative Biochemistry and Physiology B, 119:493-503 (Hafid), and further in view of U.S. Patent Number 5,198,215, issued to Bernard J. C. H. De Cueninck. Each of these references is of record in the IDS of August 27, 2003. The claims describe polynucleotides encoding multiple epitope fusion polypeptides comprising GapC protein epitopes from multiple species of *Streptococcus* bacteria.

Dale discloses a recombinant multivalent hybrid protein comprising epitopes of different serotypes of Group A streptococci bacterium. Abstract, col. 5-6. The patent states that "the hybrid molecule is immunogenic against at least more than one serotype of group A streptococci." Col. 6, lines 21-23. Thus, the patent teaches that the disclosed fusion polypeptide comprises at least two bacterial epitopes. Further, the patent specifically teaches a protein that comprises fragments of three different bacteria. Co, 18, lines 40-45; and Col. 17, lines 57-60.

Art Unit: 1648

Dale teaches that these polypeptides may be encoded by polynucleotides, and produced by the expression of the polynucleotides. See e.g., claims 33, 46, and columns 8-9. Thus, the patent provides general teachings for multiple Streptococcus epitope fusion proteins, and DNA encoding such proteins, and vectors and cells comprising the DNA.

The patent also provides for both repeating sequences and for linker sequences within the encoded proteins. Col. 6, lines 44-46; col. 6-7; and col. 16, lines 22-51. As the patent teaches that there may be repeating sequences, and that the fusion polypeptides "may be (but need not be)" fused together by linkers, the patent teaches embodiments wherein the linkers could be said to be the same or different as A, B, or C, and the same or different from each other (i.e. the fusion comprises a repeating sequence of each epitope and no other linker). Because the patent teaches specifically teaches that linkers "having 14 or more (e.g. 20) amino acids" may be used. Col. 16, lines 35-36. Thus, the patent teaches embodiments of the fusion polypeptide where A, B, and C are linked by "amino acid sequences from 1 to 1,000 amino acids). However, while the reference does teach polynucleotides encoding multiple epitope fusion polypeptides comprising epitopes of one or more bacterial species of the genus Streptococcus, it does not teach that the epitopes used are protein fragments of the GapC protein. Instead, the patent teaches the use of epitopes of the M protein. Col. 1, lines 12-16.

Fischetti teaches a streptococcal surface dehydrogenase protein on the surface of several streptococcus serological groups with Glyceraldehyde-3-phosphate dehydrogenase (GAPDH) activity. Page 2. The document further discloses that because antibodies to the protein interfere with its operations in the colonization of the bacterium, the protein and antigenic fragments thereof (from about 6 to 20 amino acid residues) are useful to inhibit streptococcal infections.

Art Unit: 1648

Page 29. As the document indicates that the disclosed protein is not a single protein, but a class of streptococcal proteins, it would be apparent to one of ordinary skill in the art that a beneficial vaccine would include multiple serotypes of the antigenic fragments. Although the document does not disclose that the GAPDH is a gapC protein, the Hafid reference teaches that the GAPDH protein of another bacterial strain is the protein encoded by the gapC gene. Comp. Biochem. Physiol., 119B p. 493, Abstract.

It would therefore have been obvious to one of ordinary skill in the art to combine the Dale and the Fischetti references to create the multiple epitope fusion protein taught by Dale, using the epitopes of the GAPDH taught by Fischetti, and therefore to create a polynucleotide encoding such a protein. As Fischetti discloses that the GAPDH protein is an effective immunogen against several groups of streptococci, but that GAPDH is a class of proteins, not a single protein, and as Dale discloses that the purpose of the fusion protein is to provide a vaccine against multiple serotypes of streptococcus, it would be obvious to one of ordinary skill in the art to use multiple epitopes of the GAPDH proteins. The motivation for doing so would be the same for the GAPDH as for the protein M- to create a vaccine effective against multiple bacterial strains.

Claims 13, 22, and 31 are obvious because one of ordinary skill in the art would recognize the named species as streptococcus bacterium. It would therefore be obvious to one of ordinary skill in the art to make a fusion protein that combines antigens for the bacterium to vaccinate against all of them simultaneously. See e.g. De Cueninck, col. 1, lines 10-22 (indicating that the streptococcus bacterium *S. uberis*, *S. dysgalactiae*, and *S. agalactiae* are all

Art Unit: 1648

causal agents for mastitis- thereby providing a motivation to combine vaccines and rendering obvious a vaccine combining antigens to these species).

Thus, the references teach the claimed polynucleotides for the purposes of producing multiple epitope fusion proteins that may be used for vaccines, and in method of screening for antibodies. Dale, supra, and col. 15, lines 38-51. In view of these teachings, the claimed polynucleotides are obvious over the prior art.

9. Claims 11, 12, 20, 21, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dale in view of Fischetti as applied to claims 10, 13, 14, 19, 22, 23, 28, 31, and 32 above, and further in view of U.S. Patent 6,391,316 issued to Potter et al. (Potter), or U.S. Patent Application Publication 2001/0014335, naming Saitoh et al. as inventors (Saitoh). Each of these references is of record in the IDS of August 27, 2003. These claims describe the polynucleotides of (e.g.) claim 10, wherein the encoded polypeptide comprises a signal sequence, and/or a transmembrane sequence. The teachings of Dale and Fischetti are described above.

The two additional references each disclose fusion proteins that comprise signal sequences, and that may comprise transmembrane sequences. Potter, Col. 5, lines 44-57, Saitoh Page 2, paragraph 31. These two references indicate that the use of signal sequences and transmembrane sequences for protein identification and production are known in the art, and would therefore be obvious to one of ordinary skill in the art. The motivation for including such sequences would be to help in the identification and isolation of the proteins once expressed

Art Unit: 1648

from the claimed polynucleotide. The references therefore render the claimed inventions obvious.

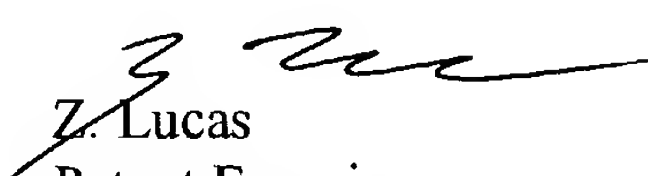
Conclusion


10. No claims are allowed. Claims 15-18, 24-27, 33-36 are objected to as depending on rejected claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
6/1/04